REMARKS

Claims 1, 3, 6-9, 11-12, 16-20, 22-26, 28-31 and 33-70 are pending in the present application. Claims 2, 4-5, 13, 15, 21, and 32 were previously canceled. Claims 10, 14, and 27 are canceled herein. Claims 1, 3, 6-8, and 30-55 are withdrawn from further consideration. Claims 9-12, 14, 16-20, 22-29, and 56-70 are currently subject to examination.

Claim 9 is amended herein to recite, "[a] kit comprising at least one biologically active molecule and at least one cellular delivery polymer . . . wherein the biologically active molecule is a nucleic acid." Support for this amendment is found, for example, in claim 10 as originally filed.

Claim 12 is amended herein to recite, "[a] complex comprising a cellular delivery polymer and an agent that is desirably taken up by cells . . . wherein the agent is at least one nucleic acid molecule or at least one polypeptide or both." Support for this amendment is found, for example, in claim 14 as originally filed.

Claims 11, 16, and 28-29 have been amended herein to provide proper antecedent basis.

It is believed that no new claims fees are due. As the present amendments to the Claims and Specification do not involve the introduction of any new matter, entry of the present amendments is respectfully requested.

Detailed Action

The Examiner stated that an amendment was received and entered on 01/19/10. Additionally, the Examiner stated that claims 56-70 were added.

The Examiner also asserted that the Applicant's election without traverse of Group 5 is acknowledged and that claims 1, 3, 6-8 and 30-55 are withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention.

Priority

The Examiner stated that the Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. § 119(e) or under 35 U.S.C. §§ 120, 121, or 365(c) is acknowledged. However, the Examiner asserted that Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e).

In particular, the Examiner asserted that the prior-filed applications, Application Nos. 60/531,399 and 60/574,131, fail to provide adequate support or enablement in the manner provided by 35 U.S.C. § 112, first paragraph, for one or more claims of the instant application. Additionally, the Examiner asserted that the prior-filed applications fail to provide support for "most of the species of nucleic acid molecules set forth in instant claims 19 and 28, e.g. mRNA, tmRNA, tRNA, rRNA, siRNA, shRNA, PNA, artificial chromosomes, cDNA, PCR products, restriction fragments, and ribozymes." Moreover, the Examiner stated that because "all claims under consideration embrace at least some of these species and do not have the benefit of support from the priority documents," the effective filing date of the claims is 12/20/04.

Applicant respectfully traverses the Examiner's assertions.

35 U.S.C. § 119(e)(1) provides, *inter alia*, an application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application shall have the same effect as though filed on the date of the provisional application filed. As provided in 35 U.S.C. § 112, first paragraph, "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same."

The written description requirement requires that an applicant's specification convey with reasonable clarity to those skilled in the art, that, as of the filing date sought, he or she was in possession of the invention. *Vas-Cath, Inc. v. Mahurkar*, 19 USPQ 2d 1111, 1116 (Fed. Cir. 1991). Compliance with the written description requirement ***does not*** require an applicant to describe ***exactly*** the subject matter claimed; rather, the description must clearly allow a person of ordinary skill in the art to recognize that he or she invented what is claimed. *Id.* (emphasis added). The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure

or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. *Eli Lilly*, 119, F. 3d at 1568, 43 USPQ 2d at 1406. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *See* MPEP § 2163. Moreover, description of a representative number of species ***does not*** require the description to be of such specificity that it would provide individual support for each species that the genus embraces. *See* MPEP § 2163.

Based upon the legal standards regarding the written description requirement under 35 U.S.C. § 112, first paragraph, Applicant submits that the prior-filed applications provide adequate support for the claims of the instant application.

Dependent claims 19 and 28 recite the complex of claim 18 wherein the nucleic acid is selected from the group consisting of mRNA, tmRNA, tRNA, rRNA, siRNA, shRNA, PNA, ssRNA, dsRNA, ssDNA, dsDNA, DNA: RNA hybrid molecules, plasmids, artificial chromosomes, gene therapy constructs, cDNA, PCR products, restriction fragments, ribozymes, antisense constructs, and combinations thereof (claim 19), and the pharmaceutical composition of claim 26, wherein the agent that is desirably taken up by cells is at least one nucleic acid selected from the group consisting of mRNA, tmRNA, tRNA, rRNA, siRNA, shRNA, PNA, ssRNA, dsRNA, ssDNA, dsDNA, DNA: RNA hybrid molecules, plasmids, artificial chromosomes, gene therapy constructs, cDNA, PCR products, restriction fragments, ribozymes, antisense constructs, and combinations thereof (claim 28).

While the Examiner asserted that the prior-filed applications fail to provide support for most of the species of the genus, nucleic acid molecules, set forth in instant claims 19 and 28, e.g. mRNA, tmRNA, tRNA, rRNA, siRNA, shRNA, PNA, artificial chromosomes, cDNA, PCR products, restriction fragments, and ribozymes, Applicant respectfully disagrees.

Specifically, with regard to shRNA, or short hairpin RNA, Application Nos. 60/531,399 and 60/574,131 disclose that the oligonucleotides may be DNAs or ***RNAs*** and may contain modified nucleotides and/or pseudonucleotides, the oligonucleotides may be single-stranded or double-stranded and linear or cyclic. (*See* Pages 21-22, lines 14-21 & lines

1-6 & Pages 21-22, ¶ 0046, emphasis added). Additionally, Application Nos. 60/531,399 and 60/574,131 state that, "oligonucleotides can form secondary and tertiary structures by self-hybridizing or by hybridizing to other polynucleotides [and] [s]uch structures can include, but are not limited to, duplexes, ***hairpins***, cruciforms, bends, and triplexes." (*See* Page 16, lines 5-8 & Page 17, ¶ 0035, emphasis added). Furthermore, Application Nos. 60/531,399 and 60/574,131 disclose that oligonucleotides may include oligonucleotides that form ***hairpin structures*** such that a duplex binding site for a transcription factor is generated. (*See* Page 17, lines 5-11 & Page 18, ¶ 0037). Thus, Applicant submits that the prior-filed applications also provide support for the species, shRNA, recited in claims 19 and 28.

With regard to PCR products, Application Nos. 60/531,399 and 60/574,131 disclose that "oligonucleotide[s] . . . [o]r a nucleic acid or its fragments . . . can be ***amplified by PCR*** or using a cloning vector or the like." (*See* Page 22, lines 11-13 & Page 22 ¶ 0047, emphasis added). Thus, Applicant submits that the prior-filed applications also provide support for the species, PCR products, recited in claims 19 and 28.

With regard to restriction fragments, Application Nos. 60/531,399 and 60/574,131 disclose that, the desired nucleic acid can be ***obtained by such procedures as cleavage with restriction enzymes*** or the like. (*See* Page 22, lines 13-15 & Page 22, ¶ 0047, emphasis added). Thus, Applicant submits that the prior-filed applications also provide support for the species, restriction fragments, recited in claims 19 and 28.

With regard to PNA, or peptide nucleic acids, Application Nos. 60/531,399 and 60/574,131 disclose that: the oligonucleotides may be DNAs or RNAs and may contain ***modified nucleotides*** and/or pseudonucleotides, the oligonucleotides may be single-stranded or double-stranded and linear or cyclic, the oligonucleotides may be modified so to be less susceptible to biodegradation, such as those containing the thiophosphoric diester bond and those containing a methyl phosphate group ***containing no electric charge***. (*See* Pages 21-22, lines 14-21 & lines 1-6 & Pages 21-22, ¶ 0046, emphasis added). The instant Specification provides that, "PNAs are analogs of nucleic acid molecules in which the backbone is a pseudopeptide rather than a sugar." (*See* Page 82, ¶ 00265). The instant Specification further provides that, "the ***neutral backbone*** of PNAs can result in stronger binding and greater specificity." (*See* Page 82, ¶ 00265, emphasis added).

Applicant submits that one of ordinary skill in the art would recognize that the applicant was in possession of the species, PNA, as recited in dependent claims 19 and 28,

from the common attributes or features disclosed in the prior-filed applications. Moreover, as previously discussed, compliance with the written description requirement ***does not*** require an applicant to describe ***exactly*** the subject matter claimed. Thus, Applicant submits the description of Application Nos. 60/531,399 and 60/574,131 also provide support for the species, PNA, recited in claims 19 and 28.

Moreover, Application Nos. 60/531,399 and 60/574,131 disclose that: the oligonucleotides may be ***DNAs or RNAs*** and may contain modified nucleotides and/or pseudonucleotides, the oligonucleotides may be ***single-stranded or double-stranded*** and ***linear or cyclic***, and the oligonucleotides may be modified so to be less susceptible to biodegradation. (*See* Pages 21-22, lines 14-21 & lines 1-6 & Pages 21-22, ¶ 0046, emphasis added). Application Nos. 60/531,399 and 60/574,131 also disclose that, "[s]uch oligonucleotides include, but are not limited to, single stranded palindromic oligonucleotides comprising one or more repeats of the enhancer sequence, ***sense and antisense oligonucleotides***." (*See* Page 17, lines 5-11 & Page 18, ¶ 0037, emphasis added). Moreover, Application Nos. 60/531,399 and 60/574,131 also disclose that, "[o]ligonucleotides can form secondary and tertiary structures by ***self-hybridizing*** or by ***hybridizing to other polynucleotides***." (*See* Page 16, lines 5-7 and Page 17, ¶ 0035, emphasis added). Additionally, Application Nos. 60/531,399 and 60/574,131 also disclose that, "the preferred dosage form includes those which are generally used in ***gene therapy***." (*See* Page 23, lines 10-12 & Page 23, ¶ 0049, emphasis added). Thus, Applicant submits that the prior-filed applications also provide support for the following species recited in dependent claims 19 and 28: ssRNA, dsRNA, ssDNA, dsDNA, DNA, RNA hybrid molecules, plasmids, gene therapy constructs, and antisense constructs.

As previously discussed, description of a representative number of species ***does not*** require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Additionally, as discussed above, satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Thus, for the reasons discussed above, Applicant submits that the prior-filed applications disclose a representative number of the species, satisfying the written description requirement for the claimed genus. As a result, Applicant submits that the genus, at least one nucleic acid, was sufficiently disclosed in the provisional applications to which the instant application

claims priority. Accordingly, Applicant respectfully requests that the Examiner award the claimed invention a priority date of December 19, 2003, which corresponds to the filing date of Application No. 60/531,399.

Moreover, Applicant submits that, contrary to the Examiner's assertions, the prior-filed applications also provide enablement to the claimed invention. The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention. *See* MPEP § 2164. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. *See* MPEP § 2164.

Application Nos. 60/531,399 and 60/574,131 disclose that the technology to be employed in the present invention may include conventional chemical methods for synthesis, biochemical methods for synthesis, or genetic engineering. (*See* Page 22, lines 7-10 & Page 22, ¶ 0047). Thus, Applicant submits that the techniques for making the nucleic acids suitable for use in the complexes or compositions of the claimed invention were known in the art at the time of filing. As a result, Applicant submits that Application Nos. 60/531,399 and 60/574,131 provide enablement to the claimed invention. Accordingly, Applicant respectfully requests that the Examiner award the claimed invention a priority date of December 19, 2003, which corresponds to the filing date of Application No. 60/531,399.

Compliance with the Sequence Rules

The Examiner stated that the application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). Further, the Examiner stated that the application fails to comply with the requirements of 37 CFR §§ 1.821 through 1.825 because the Specification, at page 113, paragraph 369, and at page 128, paragraph 421, discloses nucleotide sequences in excess of 9 bases that are not accompanied by a SEQ ID NO.

In response, paragraphs [00369] and [00421] of the Specification have been amended herein to provide proper SEQ ID NOs for the nucleotide sequences in excess of 9 bases. Thus, Applicant submits that the application is in compliance with 37 CFR §§ 1.821(a)(1) and (a)(2).

Claim Rejections - 35 U.S.C. § 102(a)

Claims 12, 14, 16, 18, 19, 20, and 22-28 are rejected under 35 U.S.C. § 102(a) as being anticipated by Reineke et al. (Molecular Therapy, (May 2004) Vol. 9, Supp. [1], pp.

S139-S139. MA 362). Claims 12, 14, 16, 18, 19, 20, and 22-28 are also rejected under 35 U.S.C. § 102(a) as being anticipated by Liu et al. (J. Am. Chem. Soc. 126: 7422-7423, 2004).

Applicant respectfully traverses these rejections.

Firstly, Applicant submits that Reineke et al. and Liu et al. are unavailable as references under 35 U.S.C. § 102(a). As previously discussed, Applicant submits that the prior-filed Application Nos. 60/531,399, filed December 19, 2003, and 60/574,131, filed May 25, 2004, provide adequate support and enablement in accordance with 35 U.S.C. § 112, first paragraph, for one or more claims of the instant application. As a result, Applicant submits that the present application bears a priority date of December 19, 2003.

According to 35 U.S.C. §102(a), "a person shall be entitled to a patent unless the invention was . . . patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." Therefore, under 35 U.S.C. §102(a), "a document is prior art only when published before the invention date." *Mahurkar v. C.R. Bard, Inc.,* 79 F.3d 1572, 1576 (Fed. Cir. 1996). As Reineke et al. bear a publication date of May 01, 2004, Liu et al. bear a publication date of May 29, 2004, and the present application bears a priority date of December 19, 2003, Applicant submits that both Reineke et al. and Liu et al. bear a publication date after the date of invention. Thus, Applicant submits that Reineke et al. and Liu et al. are improper references under 35 U.S.C. § 102(a). Accordingly, Applicant respectfully submits that the Examiner's rejections under 35 U.S.C. §102(a) are moot and should be withdrawn.

Secondly, to advance prosecution, Applicant has submitted signed declarations under 37 CFR § 1.132, asserting that Reineke et al. and Liu et al. describe the Applicant's own work. Reineke et al. and Liu et al. were cited as references under 35 U.S.C. § 102(a). When a claim of an application is rejected, "the applicant may overcome the rejection by filing a specific affidavit or declaration under 37 CFR 1.132 establishing that the article is describing the applicant's own work." *See* MPEP §715.01(c). Moreover, "[a]n affidavit or declaration by applicant alone indicating that applicant is the sole inventor and that the others were merely working under his or her direction is sufficient to remove the publication as a reference under 35 U.S.C. §102(a)." *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

Here, as shown in the signed 37 CFR § 1.132 declarations from the inventor, Theresa M. Reineke, it is clear that Theresa M. Reineke is the sole inventor and that the co-authors

cited in Reineke et al. and Liu et al. were merely working under her direction. Thus, Applicant submits that the declarations under 37 CFR §1.132 are sufficient to remove the Reineke et al. and Liu et al. printed publications as references under 35 U.S.C. §102(a).

Accordingly, it is respectfully requested that the Reineke et al. and Liu et al. references be withdrawn from the above rejections as they are not proper references under 35 U.S.C. §102(a). Since Reineke et al. and Liu et al. are the only references applied in the above rejections, Applicant respectfully submits that the rejections under 35 U.S.C. §102(a) are moot and should be withdrawn. Additionally, as claims 14 and 27 have been cancelled herein, Applicant respectfully submits that the Examiner's rejection of claims 14 and 27 under 35 U.S.C. §102(a) are moot and should be withdrawn.

Claim Rejections - 35 U.S.C. § 102(b)

Claims 12, 22, 25, 26, 56, 57, 59, and 70 are rejected under 35 U.S.C. § 102(b) as being anticipated by Akelah et al. (Eur. Poly. J. 31(9): 903-909, 1995).

Specifically, the Examiner stated that Akelah et al. disclose copolymers comprising polyamides and free hydroxyl groups formed by polycondensation of diethyl-L-tartrate with various diamines to form poly(L-tartaraamidoamine)s, including poly(L-tartaradiethylenediamine) and poly(L-tartaratriethylenediamine). The Examiner also asserted that Akelah et al. teach conjugation of an herbicide, dichlorophenoxyacetic acid (2,4-D), to the poly(L-tartaraamidoamine)s and that the herbicide is intended for delivery to cells. Thus, the Examiner concluded that Akelah et al. anticipate claims 12, 56, 57, 59, and 70. Moreover, the Examiner asserted that Akelah et al. also anticipate claims 22, 25, and 26, stating that the conjugate of Akelah et al. was formulated in an aqueous buffer solution and placed in a container.

Applicant respectfully traverses these assertions. However, to expedite prosecution, independent claim 12 has been amended herein to recite the limitations of dependent claims 17 and 28. Specifically, independent claim 12 has been amended herein to recite, "[a] complex comprising a cellular delivery polymer and an agent that is desirably taken up by cells . . . wherein the agent is at least one nucleic acid molecule or at least one polypeptide or both." Support for this amendment is found in the original claims; thus it is believed that no new matter has been entered. Additionally, claims 14 and 27 have been canceled herein to avoid redundancy and claims 17, 28, and 29 have been amended herein to provide proper antecedent basis. More particularly, claims 17, 28 and 29 have been amended to recite,

respectively, "[t]he complex of claim 12," "[t]he pharmaceutical composition of claim 26," and "[t]he pharmaceutical composition of claim 26."

As amended, Applicant submits that Akelah et al. fail to disclose the limitations recited in amended independent claim 12. Thus, Applicant respectfully requests the withdrawal of the rejection of independent claim 12 under 35 U.S.C. § 102(b). Additionally, as claims 22, 25, 26, 56, 57, 59, and 70 depend from independent claim 12, Applicant also respectfully requests the withdrawal of the rejection of these claims under 35 U.S.C. § 102(b).

Claims 9-12, 14, 16-20, and 22-29 are also rejected under 35 U.S.C. § 102(b) as being anticipated by Baker et al. (WO 01/87348).

Specifically, the Examiner stated that the term "polyhydroxylamidoamine" was given the broadest possible interpretation, asserting that is not a widely recognized term and that the instant Specification does not provide a limiting definition for the term. Additionally, the Examiner asserted that this interpretation includes molecules that include several hydroxyl groups and at least one amidoamine group; accordingly, the Examiner stated that Baker et al. teach polyamidoamine dendrimers modified with carbohydrate residues for improving dendrimer binding to target cells. Additionally, the Examiner asserted that Baker et al. teach polyhydroxyls conjugated to amidoamines and that the dendrimers of the invention can be used to form complexes with agents to form pharmaceutical compositions, further asserting that Baker et al. specifically disclose nucleic acid delivery, including antisense, oligonucleotide, and gene delivery.

Applicant respectfully traverses the Examiner's assertions.

It is well established that a rejection under 35 U.S.C. §102 requires the presence of each and every element of the claimed invention as recited in the claim. *In re Arkley*, 172 USPQ 524 (CCPA 1972).

Independent claims 9 and 12 recite, *inter alia*, a kit comprising at least one biologically active molecule and at least one cellular delivery polymer, wherein the cellular delivery polymer is selected from the group consisting of polyhydroxylamidoamine, cyclodextrin-based dendritic macromolecules, 1,3-dipolar addition polymers, and carbohydrate-containing biodegradable polyesters (claim 9) and a complex comprising a cellular delivery polymer and an agent that is desirably taken up by cells, wherein the cellular delivery polymer is selected from the group consisting of polyhydroxylamidoamine,

cyclodextrin-based dendritic macromolecules, 1,3-dipolar addition polymers, and carbohydrate-containing biodegradable polyesters (claim 12).

With regard to the Examiner's assertion that Baker et al. teach the limitation "polyhydroxylamidoamine" recited in independent claims 9 and 12, Applicant respectfully disagrees. The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004).

The instant Specification provides that, "the term polymer includes poly(hydroxylamidoamine), dendritic macromolecules, and also carbohydrate-containing biodegradable polyesters." (*See* Page 16, ¶ 0057). The instant Specification also provides that poly(hydroxylamine)s include but are not limited to poly(glycoamidoamine)s, (any carbohydrate) and poly(L-tartaramidoamine)s. (*See* Page 16, ¶ 0058). Moreover, the instant Specification provides that the poly(hydroxylamine)s may be prepared by condensation of an appropriately substituted diester or other substitutions that react with amines such as acid chlorides, carboxylic acids, lactones, anhydrides, etc. and an appropriately substituted diamine comonomer. (*See* Page 16, ¶¶ 0058-0059). Thus, contrary to the Examiner's assertions, Applicant submits that the instant Specification provides sufficient guidance as to the meaning of the term "poly(hydroxylamidoamine)s" recited in independent claims 9 and 12.

In light of the instant Specification, Applicant further submits that Baker et al. fail to teach the element "poly(hydroxylamidoamine)s" as recited in independent claims 9 and 12. Specifically, Applicant submits that, contrary to the Examiner's assertion, the teaching in Baker et al. of polyamidoamine ***dendrimers*** modified with carbohydrate residues, is not the same as the "polyhydroxylamidoamine" recited in Applicant's invention. The instant Specification clearly distinguishes between polyhydroxylamidoamines and dendrimers, providing that, "the term polymer includes poly(hydroxylamidoamine) [and] dendritic macromolecules." (*See* Page 16, ¶ 0057). Thus, Applicant submits that the polyamidoamine dendrimer modified with carbohydrate residues disclosed in Baker et al. is not the same as, nor suggestive of, the polyhydroxylamidoamine recited in independent claims 9 and 12.

Thus, Applicant submits that Baker et al. fail to disclose the limitations recited in independent claims 9 and 12. As a result, Applicant respectfully requests the withdrawal of the rejection of independent claims 9 and 12 under 35 U.S.C. § 102(b). Additionally, as claims 11, 14, 17-20, and 22-29 depend from independent claims 9 and 12, Applicant also respectfully requests the withdrawal of the rejection of these claims under 35 U.S.C. § 102(b). Finally, as claims 10, 14, and 27 have been canceled herein, Applicant submits that the Examiner's rejection of these claims under 35 U.S.C. § 102(b) is moot and respectfully requests its withdrawal.

Claim Rejections - 35 U.S.C. § 103

Claims 9, 12, 22, 25, 26, and 56-70 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Akelah et al. (Eur. Poly. J. 31(9): 903-909, 1995).

With regard to independent claim 12, the Examiner stated that Akelah et al. teach copolymers comprising polyamides and free hydroxyl groups formed by polycondensation of diethyl-L-tartrate with various diamines. Additionally, the Examiner asserted that absent evidence to the contrary, the aqueous buffer is a pharmaceutically acceptable excipient and the composition is a pharmaceutical composition. As a result, the Examiner stated that Akelah et al. anticipate and render obvious claims 12, 22, 25, 26, 56, 57, 59, and 70.

Applicant respectfully traverses these assertions. As previously discussed, independent claim 12 has been amended herein to recite, "[a] complex comprising a cellular delivery polymer and an agent that is desirably taken up by cells . . . wherein the agent is at least one nucleic acid molecule or at least one polypeptide or both." Applicant finds no teaching or suggestion in Akelah of a complex comprising a cellular delivery polymer and an agent, wherein the agent is at least one nucleic acid molecule or at least one polypeptide, or both, as required by instant claim 12. Thus, Applicant submits that Akelah et al. fail to teach or suggest all of the limitations of amended independent claim 12. Accordingly, Applicant respectfully requests the withdrawal of the rejection of independent claim 12 under 35 U.S.C. § 103. Additionally, as claims 22, 25, 26, 56, 57, 59 and 70 depend from independent claim 12, Applicant also respectfully requests the withdrawal of the rejection of these claims under 35 U.S.C. § 103.

With regard to claim 58, the Examiner stated that diethyl-L-tartrate diester is structurally similar to the recited dimethyl-L-tartrate diester, and also stated that a prima facie

case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities.

Applicant respectfully traverses the Examiner's assertions. Specifically, Applicant submits that because Akelah et al. fail to teach or suggest the limitations recited in independent claim 12, from which claim 58 depends, claim 58 is also not obvious over Akelah et al. Applicant respectfully requests the withdrawal of the rejection of claim 58 under 35 U.S.C. § 103.

With regard to claims 60-69, the Examiner stated that because the carbohydrate moieties differ from the carbohydrate moiety of Akelah et al. by addition of a diol, there is a presumed expectation that the compounds possess similar properties.

Applicant respectfully traverses the Examiner's assertions. Further, Applicant submits that because Akelah et al. fail to teach or suggest the limitations recited in independent claim 12, from which claims 60-69 depend, claims 60-69 are also not obvious over Akelah et al. Applicant respectfully requests the withdrawal of the rejection of claims 60-69 under 35 U.S.C. § 103.

With regard to independent claim 9, the Examiner stated that it would have been obvious to one of ordinary skill in the art at the time the invention was made to organize the elements of the invention of Akelah et al. into a kit because one of skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

Applicant respectfully traverses these assertions. However, to expedite prosecution, independent claim 9 has been amended herein to recite the limitations of dependent claim 10. Specifically, independent claim 9 has been amended herein to recite, "[a] kit comprising at least one biologically active molecule and at least one cellular delivery polymer . . . wherein the biologically active molecule is a nucleic acid." Support for this amendment is found in the original claims; thus it is believed that no new matter has been entered. Additionally, claim 10 has been canceled herein to avoid redundancy and claim 11 has been amended herein to provide proper antecedent basis. More particularly, claim 11 has been amended to recite, "[t]he kit of claim 9."

As amended, Applicant submits that Akelah et al. fail to teach or suggest the limitations recited in amended independent claim 9. Thus, Applicant respectfully requests the withdrawal of the rejection of independent claim 9 under 35 U.S.C. § 103.

CONCLUSION

It is believed that the above represents a complete response to the Office Action dated February 25, 2010. Applicant therefore respectfully requests that examination on the merits be commenced. It is believed that no additional fees are required, but in the event this is incorrect, please charge any additional fees required in connection with the present Amendment to Deposit Account No. 04-1133.

Respectfully submitted,

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